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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,782	07/13/2001	Suresh K. Tikoo	293102002900	1838

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EXAMINER
FOLEY, SHANON A

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/27/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/904,782	TIKOO, SURESH K.	
	Examiner	Art Unit	
	Shanon Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 July 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-38* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, 14-21, drawn to an adenovirus vector comprising an intron and a heterologous transgene, classified in class 435, subclass 320.1 and class 424, subclass 233.1.

If applicant elects group I, applicant is further required to elect one of the following specific transgenes A-D:

A) pathogen, claims 9, 28, 33 and 34

B) virus protein, claims 10, 11, 29 and 30

C) bacterial protein, claims 12 and 31

D) parasite, claims 13 and 32

Claims 1-8 and 14-21 are linking claims and will be examined with any of the patentably distinct groups A-D elected for group I.

II. Claims 22-24, drawn to a method of making an adenovirus vector, classified in class 435, subclass 91.41.

III. Claims 25-27, drawn to a method of making an adenovirus, classified in class 435, subclass 70.1.

IV. Claim 35, drawn to a method of treating or ameliorating symptoms of an RNA viral infection, classified in class 424, subclass 202.1.

V. Claim 36, drawn to a method of treating or ameliorating symptoms of a DNA viral infection, classified in class 424, subclass 202.1.

VI. Claim 37, drawn to a method of treating or ameliorating symptoms of a bacterial infection, classified in class 424, subclass 201.1.

VII. Claim 38, drawn to a method of treating or ameliorating symptoms of a parasitic infection, classified in class 424, subclass 265.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions A-D are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to structurally and functionally distinct transgenes that are derived from different pathogenic organisms. None of the transgenes comprise the same nucleotides that encode a protein and none of the products encoded by the transgenes will elicit the same immune response. Each of the transgenes have different functions and different effects because they encode different products and each of the products encoded will have a different structure and effect on an immune system. Therefore, each of the transgenes are independent and patentably distinct.

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the method of making can be used to make materially different products, i.e. each of the adenovirus vectors encoding one of the patentably distinct transgenes, A-D. Alternatively, the products of group I, A-D in the alternative can be made by the process of group III.

Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the method of making can be used to make materially different products, i.e. each of the adenovirus vectors encoding one of the patentably distinct transgenes, A-D. Alternatively, the products of group I, A-D in the alternative can be made by the process of group II.

Inventions IV-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the methods involve using distinct products that are unrelated in structure and function because each of the products are derived from a different pathogen. Further, none of the products can be used together in any of the disclosed methods because each of the methods are drawn to treating and ameliorating disease in different populations.

Inventions I, A-D in the alternative and IV-VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of group IV can be practiced with an adenovirus encoding any transgene from any RNA virus of group IA. As each of the RNA viruses are structurally, functionally, etiologically and pathogenically distinct from each other, the method can be practiced with materially different adenoviruses expressing different

transgenes from any RNA virus. This same reasoning applies for group IB, a DNA virus used in group V, group IC, a bacterial transgene used in the method of group VI, and group ID, a parasitic transgene used in the method of group VII. Alternatively, each of the products, IA-ID can be used in a different process, such as making an adenovirus encompassed by group III.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and a divergent subject matter. A search for one group does not include a search for another. Therefore, a restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley
June 26, 2003